

**REMARKS/ARGUMENTS**

Claims 1-19 are pending in the instant application.

The following remarks are believed to be fully responsive to the Office Action.

**DOUBLE PATENTING**

Claims 8-12 and 14 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 3-7, 11, 13, 15 of co-pending Application No. 10/552,134. In response, Applicants submit that claims will be amended or cancelled if the instant application is indicated to be allowable.

Further, claims 1, 2 6-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 11/358,681. In response, Applicants submit that a terminal disclaimer will be filed once the instant application is indicated as allowable.

Still further, claims 1-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/552,134. In response, Applicants submit that a terminal disclaimer will be filed once the instant application is indicated as allowable.

**THE REJECTIONS UNDER 35 U.S.C. § 103**

**SHOULD BE WITHDRAWN**

Claims 1-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Griffiths et al., WO03/059397A2 (“Griffiths”) in view of Bottcher et al., US 5,439,863 (“Bottcher”) and further in view of Maier-Borst et al., GB2056471A (“Maier-Borst”). In response, Applicants submit that the rejections should be withdrawn for the reasons stated below.

Applicants note that on page 5 of the current Office Action the Examiner states in part that it “would have been obvious to utilize (try) the microwave synthesis technique”. Applicants respectfully disagree. It would not have been obvious to try since Bottcher teaches other inputs of energy through the effect of ultrasound or a laser beam. Bottcher does not discuss how microwave technology could be used as an input of energy. Furthermore, Applicants believe it is clear that Bottcher does not deem these inputs of energy as important parts of its patent. Bottcher presents using three separate inputs of energy on merely two lines throughout its entire patent. Bottcher also does not teach that microwaves are preferred over using ultrasound or laser beams as inputs of energy. Bottcher does not disclose, teach, or suggest using a microwave oven as disclosed in the present invention to enhance or improve efficiency and reproducibility of the neutral metal complex salt formation. If Bottcher used the same microwave technology, such as a microwave oven, utilized in the present invention then Bottcher would have found that the use of microwave activation substantially improves the efficiency and reproducibility of its neutral metal

complex salt formation. Accordingly, Bottcher teaches away from the present invention. As noted by the Federal Circuit: A reference may be said to teach away when a person of ordinary skill, upon [examining] the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. (emphasis added).

*Para-Ordnance Mfg. v. SGS Importers Int'l*, 73 F.3d 1085 (Fed. Cir. 1995).

Applicants further respectfully point out that it is well settled in the law that a reference must be considered not just for what it expressly teaches, but also for what it fairly suggests to one who is unaware of the claimed invention. *In re Baird*, 16 F.3d 380, (Fed. Cir. 1994).

Bottcher clearly teaches away from the present invention. Unlike the present invention, the objective of Bottcher is aimed at a process of preparing a neutral metal complex salt with additional coordinated ligands comprising reacting a complex-forming metal salt with a chelating ligand and a Lewis base in water and the optional presence of a solubilizer and an inorganic auxillary base which forms a soluble salt an acid radical of the metal salt. Bottcher does not use the microwave activation technique disclosed in the present invention to carry out the coordination chemistry. Applicants note that “the prior art itself must provide a motivation or reason for the worker in the art, without the benefit of the Applicant’s specification, to make necessary changes in the reference device”. See, *Ex parte Chicago Rawhide Manufacturing Co.*, 226 U.S.P.Q. 438 (PTO Bd. App. 1984).

Furthermore, even if assuming Griffiths in view of Bottcher are properly combinable, the references still have to be combinable with Maier-Borst.

On the last paragraph of page 5 in the present Office Action, the Examiner states that “It would have been obvious to utilize (try) an anion exchanger of Maier-Borst et al. to separate  $^{68}\text{Ga}$  from its parent nuclide....”. Applicants respectfully disagree. It would not have been obvious to try since the objective of Maier-Borst was to synthesize an anion exchange resin for the separation of gallium-68 from germanium-68 thus avoiding the use of EDTA for elution as it was done before the 1980s. Its aim does not collide with our claims 1-19 and the comparison is not relevant. Unlike Maier-Borst, in the present invention, gallium-68 is eluted from a commercial generator already in ionic form. In particular our claims 1-19 consider: i) The preconcentration of gallium-68 which is needed for the efficiency of the labeling complexing reaction. Namely, the specific radioactivity for the chelator conjugated peptide labeling was increased 200-fold. ii) The volume was decreased 30 – fold, namely, from 6 mL to 200  $\mu\text{L}$ . This makes a 30 – fold increase in peptide or any other macromolecule concentration. iii) The chelating  $^{68}\text{Ga}$ -labeling reactions are sensitive to the presence of competing metal ions therefore it is important to purify the  $^{68}\text{Ge}/^{68}\text{Ga}$  generator eluate from those elements. The ability of metal ions to form complexes with hydrochloric acid differs. The adsorbability of the negatively charged complexes of metals differs as well. Taking into account that the preconcentration procedure is based on the gallium ion ability to form  $\text{GaCl}_4^-$  complex, gallium can be purified from the competing metal ions using the anion-exchanging column.

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It is therefore respectfully submitted that the 35 U.S.C. 103(a) rejections of claims 1-19 as being unpatentable over Griffiths in view of Bottcher in further view of Maier-Borst be withdrawn.

### **CONCLUSION**

In view of the remarks herein, Applicants believe that each ground for rejection or objection made in the instant application has been successfully overcome or obviated, and that all the pending claims are in condition for allowance. Withdrawal of the Examiner's rejections and objections, and allowance of the current application are respectfully requested.

The Examiner is invited to telephone the undersigned in order to resolve any issues that might arise and to promote the efficient examination of the current application.

Respectfully submitted,

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